REMARKS

In response to the non final Office Action mailed 25 June 2002, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application is respectfully requested.

Claim Objections

Claim 16

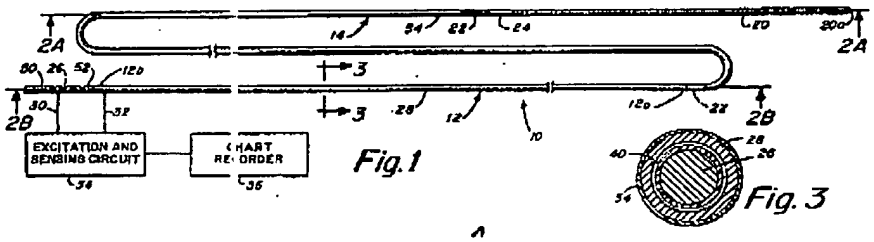
Claim 16 has been amended to delete the recitation of "of" in line 9 of the claim.

Rejections Under 35 U.S.C. §102

Claims 2-5, 9-13, 15-19 and 22-42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Vogel, et al., U.S. Patent No. 4,957,110 (Vogel).

Examiner Szmal relies upon Vogel to disclose in relevant part "a catheter having a stenosis reducing member; a port for introducing a blood property change; sensors that provide a signal as claimed ... see Col. 8, Lines 24-66 and Col. 9, Lines 5-47." [Paper 19, Page 2]

The inventive aspect of Vogel is a guidewire having electrodes for measuring blood flow and vessel cross section. The guidewire of Vogel does not include a stenosis reducing member nor a port for introducing a blood property change. Rather, Vogel merely discloses a proximal electrode 22 and a distal electrode 20 along a guidewire 10. Specifically, Vogel is directed to a small diameter, steerable guidewire that is provided with a pair of electrodes for measuring vessel cross-section and coronary blood flow. (Col. 1, Lines 10-12)

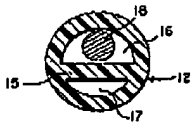


U.S. Patent Sep. 18, 1990

Examiner Szmal asserts Vogel discloses each of the limitations of the present claims, citing Col. 8, Lines 24-66 and Col. 9, Lines 5-47.

Vogel does not disclose a dilatation catheter having a blood property sensor. The Vogel guidewire is recited as being used in conjunction with a dilatation catheter of U.S. Patent No. 4,545,390. The Vogel guidewire is slideably received within a lumen of the dilatation catheter. That is, the Vogel guidewire can be used in cooperation with a dilatation catheter, wherein the dilatation catheter is described in U.S. Patent No. 4,545,390. (Col. 8, Lines 24-30) A cross section of the dilatation catheter in U.S. Patent No. 4,545,390 is:

Fig.3



where reference 12 is the dilatation catheter of the '390 patent and reference 18 is the Vogel guidewire.

The dilatation catheter 12 of the '390 patent includes the stenosis reducing member and main lumen 16, and is used in combination with the separate and independent Vogel guidewire, wherein the Vogel guidewire includes the electrodes for measuring a blood parameter. The Vogel guidewire does not include a stenosis reducing member and the dilatation catheter does not include a sensor.

Vogel states the guidewire 10 axially extends and travels through the main lumen of a separate and independent dilatation catheter. That is, the guidewire is axially (longitudinally) translatable relative to the dilatation catheter.

Specifically, Vogel states,

> As the stenosis or obstruction is approached, the guidewire is advanced independently of the dilatation catheter in order to locate the guidewire with a high degree of precision with respect to the stenosis.

Vogel expressly requires and employs the sensors of the guidewire to move relative to and independently of the dilatation catheter and thus the stenosis reducing member.

In fact, the Vogel continues,

> The guidewire is advanced to the stenosed region by a combination of pushing and rotation or steering of its proximal end.

After a measurement of the vessel has been taken, the dilatation catheter is then again moved relative to the guidewire. Specifically,

> Then, the dilatation catheter is advanced over the guidewire until the balloon is located within the obstruction

Further, Vogel actually translates the dilatation (balloon) catheter relative to the electrodes after the dilatation procedures.

> After the dilatation procedure has been completed, the balloon catheter is withdrawn, at least partially, and the electrodes 20 and 22 are again positioned in the stenosed region.

Therefore, Vogel requires relative movement between the electrodes of the guidewire and the dilatation catheter.

Claims 9-14

Independent Claim 9 recites in part "a catheter body having a stenosis reducing member . . . a port in the catheter body . . . and a sensor affixed to the catheter body . . . "

As set forth in the prior discussion of Vogel, the catheter body employed in Vogel does not include a sensor, but rather the steerable guidewire that is disposed for axial translation within and along the catheter includes the sensors. Therefore, Vogel does not disclose a sensor affixed to a catheter body, wherein the catheter body has a stenosis reducing member.

The absence of this limitation precludes Vogel from sustaining the rejection of Claim 9 under 35 U.S.C. §102. As Claims 10-15 depend from Claim 9 and include all limitations thereof, these claims are also in condition for allowance.

Claim 15

Independent Claim 15 recites in part a "catheter having means for performing a vascular corrective procedure, a dilution indicator port and a ... downstream sensor a fixed distance from the indicator port ... "

As the assembly described in Vogel requires and employs a stenosis reducing member and dilution indicator port being longitudinally (axially) moveable relative to the sensor of the steerable guidewire, the above recited limitation is not present in Vogel and in fact is expressly contrary to Vogel. Therefore, applicant respectfully submits Claim 15 is in condition for allowance. As Claim 38 depends from Claim 15, and includes all the limitations thereof, Claim 38 is also in condition for allowance.

Claim 16

Independent Claim 16 recites in part "introducing a first change in a blood property in a blood flow outside the catheter at *a fixed distance* from the blood property sensor." [emphasis added]

The blood property sensor of Vogel is disposed on the steerable guidewire and the port for introducing a dilution indicator is through the terminal end of the separate and axially translatable dilatation catheter. Thus, there can be no introducing a first change in the blood property in the blood flow outside the catheter at a fixed distance from the blood property sensor.

As this limitation is absent from the cited reference, applicant respectfully submits Claims 16 is in condition for allowance.

As Claims 17, 18, 39 and 40 depend from Claim 16 and include all limitations thereof, these claims are also believed in condition for allowance.

Claim 19

Independent Claim 19 recites in part "inserting a catheter into a vessel... employing the catheter to perform a vascular correction in the vessel . . . detecting passage of the first blood property change passed a downstream sensor *on the catheter* . . . "

That is, Claim 19 recites a catheter that performs the vascular correction and has a sensor *on the catheter* for detecting passage of the first blood property change.

As Vogel employs a steerable guidewire to detect passage of a blood property change and the separate and axially translatable dilatation catheter is used to perform the angioplasty, applicant respectfully submits Claim 19 is in condition for allowance. As Claim 41 depends from Claim 19 and includes all the limitations thereof, claim 41 is also in condition for allowance.

Claim 22

Independent Claim 22 recites in part, "a catheter . . . and a blood parameter sensor connected to the catheter and spaced a fixed distance from the blood parameter altering section."

That is, the sensor and blood parameter altering section are spaced a fixed distance apart.

In contrast, the assembly of Vogel employs and requires sensors on a steerable guidewire which is axially translatable relative to the dilatation catheter having the indicator dilution port.

Therefore, the absence of this limitations precludes the cited reference from sustaining rejection under 35 U.S.C. §102.

As Claims 23-24 depend from Claim 22 and include all limitations thereof, these claims are also believed in condition for allowance.

Claim 25

Independent Claim 25 recites in part, "locating a blood parameter sensors a fixed distance downstream of the altering section."

As Vogel requires a variable and adjustable distance between the steerable guidewire and the balloon of the dilatation catheter, this limitation is absent from the cited reference. The absence of this limitation precludes Vogel from sustaining the rejection under 35 U.S.C. §102.

As Claims 26-29 and 42 depend from Claim 25 and include all limitations thereof, these claims are also in condition for allowance.

Claim 34

Independent Claim 34 recites in part, "an elongate catheter having a stenosis reducing member, a blood property change port ... and a downstream sensor *affixed to the catheter.*

The recited sensor affixed to the catheter (which includes a stenosis reducing member) is contrary to Vogel. Therefore, applicant respectfully submits Claim 34 is in condition for allowance. As Claims 2-6,30-33 and 36 depend from Claim 34 and include all limitations thereof, these claims are also believed in condition for allowance.

Claim 35

Independent Claim 35 recites in part, "a catheter having means for increasing the effective size of a portion of vascular passage . . . and a downstream blood property sensor affixed to the catheter."

As Vogel does not disclose or suggest a blood property sensor affixed to a catheter having a means for increasing the effective size of a portion of the vascular passage, Claim 35 is in condition for allowance.

As Claims 37 depends from Claim 35 and includes all limitations thereof, this claim is also in condition for allowance.

Therefore, applicant respectfully submits all the pending claims, Claims 2-6, 9-19 and 22-42 are in condition for allowance and such action is earnestly solicited. If, however, Examiner Szmal feels that any further issues remain, he is cordially invited to call the undersigned so that such matters can be promptly resolved.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES

In the Claims:

Claim 1. (Previously cancelled).

2. (*Previously Once* Amended) The apparatus of Claim 34, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

3. (*Previously Once* Amended) The apparatus of Claim 34, further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

4. (*Previously Once* Amended) The apparatus of Claim 34, wherein the blood property change port includes an aperture for introducing a blood property variant.

5. (*Previously Once* Amended) The apparatus of Claim 34, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

6. (*Previously Once* Amended) The apparatus of Claim 34, wherein the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient.

9. (Thrice Amended) A stenosis reducing catheter, comprising:

(a) a catheter body having a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port in the catheter body for inducing a blood property change to blood flowing external to the stenosis reducing catheter; and

(c) a sensor affixed to the catheter body and spaced from the blood property change port for providing a signal corresponding to a change in a blood property external to the stenosis reducing catheter, the signal corresponding to a relationship

of flow rate = $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

10. The catheter of Claim 9, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

11. (*Previously Once* Amended) The catheter of Claim 9, further comprising a controller operably connected to the sensor to calculate the flow rate corresponding to the signal from the downstream sensor.

12. The catheter of Claim 9, wherein the port includes an aperture for introducing a blood property variant.

13. The catheter of Claim 9, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

14. The catheter of Claim 9, wherein the port includes one of a heat sink and a heat source for creating a local temperature gradient.

15. (Fourthly Amended) An apparatus for determining blood flow, comprising:

(a) a dilution indicator source;

(b) a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor a fixed distance from the indicator port for producing a signal corresponding to passage of the dilution indicator external to the catheter; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor, the controller selected to calculate the blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

16. (Fourthly Amended) A method for quantitatively measuring a reduced stenosis induced flow change, comprising:

(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property in a blood flow outside the catheter at a fixed distance from the blood property sensor and upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis [of] in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to (i) the detected passage of the first change in the blood property; (ii) the second change in the blood property; and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

17. (Once Amended) The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a first catheter having a stenosis reducing member and a second catheter having the blood property sensor, the first catheter and the second catheter being connected to locate the blood property sensor at a fixed location relative to the stenosis reducing member.

18. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and the blood property sensor.

19. (*Previously Thrice* Amended) A method of monitoring blood flow during a vascular corrective procedure, comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change into a blood flow outside the catheter;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor, and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

22. (Thrice Amended) An apparatus for determining an intra-procedural blood flow in a corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter located to alter a blood parameter external to the catheter;

(c) means for effecting the corrective procedure; and

(d) a blood parameter sensor connected to the catheter and spaced a fixed distance from the blood parameter altering section to sense the altered blood parameter external to the catheter and provide a signal for determining a blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

23. The apparatus of Claim 22, wherein the blood altering section includes one of a port and a temperature gradient generator.

24. The apparatus of Claim 22, further comprising a controller connectable to the altering section and the blood parameter sensor to calculate the blood flow.

25. (Thrice Amended) A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel to alter a blood parameter in a blood flow contacting the vessel;

(b) locating a blood parameter sensor a fixed distance downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor, the determined blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

26. The method of Claim 25, wherein performing the stenosis reducing procedure includes angioplasty.

27. The method of Claim 25, further comprising locating the blood parameter sensor to reduce wall effects from the vessel.

28. The method of Claim 25, further comprising rotating the blood parameter sensor with respect to the vessel to reduce wall effects from the vessel.

29. The method of Claim 25, further comprising locating a plurality of blood parameter sensors in the vessel.

30. (*Previously Once* Amended) The apparatus of Claim 34, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

31. (*Previously Once* Amended) The apparatus of Claim 34, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

32. The catheter of Claim 35, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

33. The catheter of Claim 35, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

34. (Twice Amended) An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port located to alter a blood property outside the catheter and a

downstream sensor affixed to the catheter and spaced from the port for producing a signal corresponding to the blood property in a blood flow in the vessel, and the correspondence relates blood flow to $=\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

35. (Twice Amended) An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port and a downstream blood property sensor affixed to the catheter; and

(b) a controller operably connected to the blood property sensor for calculating a blood flow through the vascular passage corresponding to a signal from the blood property sensor and corresponding to the relation $AF=\frac{V}{\int C(t)dt}$ where AF corresponds to the blood flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve.

36. (*Previously New*) The apparatus of Claim 34, wherein the volume of indicator introduced is one of a bolus and a constant infusion.

37. (*Previously New*) The apparatus of Claim 35, wherein the volume of indicator introduced is one of a bolus and a constant infusion.

38. (*Previously New*) The apparatus of Claim 15, wherein the dilution indicator source is selected to introduce one of a bolus injection and a constant infusion.

39. (*Previously New*) The method of Claim 16, wherein introducing the first change in the blood property includes introducing one of a bolus injection and a constant infusion.

40. (*Previously New*) The method of Claim 16, wherein introducing the second change in the blood property includes introducing one of a bolus injection and a constant infusion.

41. (*Previously New*) The method of Claim 19, wherein introducing the first blood property change includes introducing one of a bolus injection and a constant infusion.

42. (*Previously New*) The method of Claim 25, further comprising altering the blood property by introducing one of a bolus injection and a constant infusion.

43. (New) A catheter comprising:

(a) an elongate catheter body having an inflation lumen and an indicator lumen, the indicator lumen including a lateral exit port located along a side of the catheter body;

(b) an inflatable balloon fluidly connected to the inflation lumen; and

(c) a dilution sensor fixedly connected to the catheter body at a location spaced from the exit port.